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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,283	01/11/2002	Rymond C. Crippen	P 283269	4563

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EXAMINER
BRUNSMAN, DAVID M

ART UNIT	PAPER NUMBER
1755	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/042,283	CRIPPEN ET AL.	
	Examiner	Art Unit	
	David M Brunsman	1755	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): see attachment.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☒ affidavit, b)☒ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *none*.

   Claim(s) rejected: *49-89*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

David M Brunsman
Primary Examiner
Art Unit: 1755

Applicant's response including amendment and declaration under 1.132 has been carefully considered. The rejection of claims 43-49 under section 112 is withdrawn in view of applicant's amendment removing the objected to language. The rejection under section 102(b) over JP 04-096996 and "Sport Horse Supreme" are withdrawn in view of their failure to teach or suggest a single dosage unit of 100-800 mg.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-53, 56, 57, 60-63, 68-73, 78-83, 88 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaser®

Claims 50-53, 56, 57, 60-63, 68-73, 78-83, 88 and 89 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

The reference teaches a product for treatment of hangovers comprising caplets (capsule/tablets) each containing 325mg activated calcium carbonate (limestone), 175mg activated carbon and 0.5 mg Vitamin B12. The polysaccharides present in the caplet formulations are considered to be rehydration agents as they hold ambient moisture and no definition or example of "re-hydrating agents" is found in the instant specification to contradict this. Applicant has not contested the content of this reference. Applicant asserts that the reference refers to closed clinical studies done to investigate the effects of the formulation. As set forth in earlier office actions, determination of public use is a highly fact based process that must be supported by objective evidence. The evidence of record is insufficient to support applicants assertion the admitted use for five years prior to the publication of the reference was not public. Declarant in paragraph 4 states the reference

"to the best of my knowledge, appears to be a printed version of portions of our website". This phrasing makes it less than fully clear that the use in the reference is, in fact, that discussed in paragraphs 5-8 of the declaration. There is no factual evidence of record that the exhibits apply to the invention as claimed. There is no factual evidence of record to compare the scope of the claimed invention to that of the use disclosed in the reference. The declaration states that the attached "Confidentiality Agreement" governed the parties conducting the studies but does not provide evidence that said agreement was signed by all parties. There is no mention that the subjects of the study were subject to a confidentiality agreement. Furthermore, an invention may be found to have been used by the public even if the inner workings thereof were not revealed. All facts must be considered in a determination of public use. The record must address the time, place and circumstances of the use. See MPEP 2133.03(a)B. The declaration filed does not specifically address the level and character of the "supervision" of paragraph 6. The declaration does not address the extent and timing of the clinical studies performed and their relation to the critical date. The declaration does not address the circumstances of the studies including the length of the test period, its relation to studies of other such products, the number of subjects, any payments made, what variable were measured and which records kept. See MPEP 2133.03(a); Moleculon Research Corporation v, CBS, Inc., 229 USPQ 805; Ex Parte C, 27 USPQ2d 1492 and; TP Laboratories, Inc. v. Professional Positioners, Inc. et al., 220 USPQ 577.

An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as set forth above.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 58, 59, 64, 65, 74, 75, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaser®, as applied above.

The difference between the reference and these claims is the inclusion of pharmaceutical such as Olanzapine. The instant specification clearly indicates this compound is known for treatment of alcohol addiction. It would have been obvious to one of ordinary skill in the art to add a compound to treat alcohol addiction to a composition for treating symptoms of alcohol overuse because the consumers of Olanzapine would be expected to desire relief of their acute symptoms. The difference between the reference and claim 23 is the combination of treatment for alcohol abuse with administration of the instant product. It would have been obvious to one of ordinary skill in the art to treat alcohol addition in combination with administering a composition for treating symptoms of alcohol overuse because those undergoing addiction treatment would be expected to desire relief of their acute symptoms.

Claims 54, 55, 66, 67, 76, 77, 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaser™, as applied above in view of the goaskalice.Columbia.edu article "Hangover-Helping Product".

The difference between the primary reference and the instant claims is the inclusion of Vitamin B-1 in the product. The Hangover-Helping Product article teaches that the effects of a hangover may be treated with Thiamin (B-1). It would have been obvious to

one of ordinary skill in the art to add Thiamin to the product of the primary reference because it is known in the art as effective to treat hangovers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M Brunsman whose telephone number is 571-272-1365. The examiner can normally be reached on M, W, F, Sa; 6:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on 571-272-1362. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M Brunsman
Primary Examiner
Art Unit 1755

DMB